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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,339	01/26/2004	Shawn R. Feaster	034047.003DIV1 (W 00-23B)	7108

53502 7590 04/02/2009

OFFICE OF THE STAFF JUDGE ADVOCATE (SKS)
U.S. ARMY MED. RESEARCH & MATERIEL COMMAND
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FORT DETRICK, MD 21702-5012

EXAMINER	
SHEN, BIN	
ART UNIT	**PAPER NUMBER**
1657	

MAIL DATE	DELIVERY MODE
04/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,339	FEASTER ET AL.	
	Examiner	Art Unit	
	BIN SHEN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-36 and 39* is/are pending in the application.

4a) Of the above claim(s) *31-34 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-30, 35, 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of the Claims

Claims 29-36 and 39 have been presented for examination.

Claims 31-34 and 36 remain FINALLY withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 31 May 2006. Claims 29-30, 35 and 39 are examined on the merits.

The **finality** of the Office action of 14 Aug 2008 is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-30, 35, 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim29, the word "means" is preceded by the word(s) "determining" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). The phrase "means for" is modified by some structure recited in the claim (lines 7-21), but it is unclear whether the recited structure is sufficient for performing the claimed determining function. Applicant is required to clarify whether the limitation is invoking 112, 6th paragraph.

Since it is unclear the recited structure in the claim would preclude application of 112, 6th paragraph, the prior art rejection is applied until the applicant clarifies whether the limitation is invoking 112, 6th paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Doretti et al. (Applied Biochemistry and Biotechnology 1998;74:1-12).

Doretti et al. teach an enzyme biosensor (read as a device; page 12) for the determination (read as detecting/measuring) of cholinesterase on polymer membrane (see abstract). The biosensor teaches means to add (same function as a sealed chamber, see page 2, line 11-14) the plurality of substrates to a plurality of aliquots of the test sample (read as means for adding substrates to test sample), and means to detect/measure activities/concentrations of different substrates (read on as measuring reaction rates, see page 2, 7th paragraph) by measuring the reaction rates ampereometrically (see Fig. 1, Fig. 3 and Table 1).

Additionally, the claimed device in claim 29 read on as a spectrophotometer see page 5, 3rd full paragraph which comprises a means for adding substrates (the cover), a means for measuring reaction rates (the optics and photodetector) and means for determining the activity (the output of the spectrophotometer to a strip chart or data collection means).

The functional intended use with diluting, calculating and extracting sensitivity coefficients does not materially change the device and accordingly is given no patentable weight. That is the device is the same whether these activities are practiced or not. The device can be used in alternative measurements, particularly the spectrophotometer which can be used to obtain a spectrum of other molecules.

Therefore, the cited reference is deemed to anticipate the instant claims above.

Applicant's arguments filed 1/14/2009 have been fully considered but they are not persuasive.

Applicant argues that the device of Doretti does not teach or suggest the claimed invention because the device is not capable of measuring a protein or a plurality of proteins in a sample.

It is the examiner's position that the present invention claims a device with means for adding/measuring/determining, however the "means for" are not modified by sufficient structure, material, or acts for achieving the specified function, thus it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). Doretti's teaching of measuring reaction rates is considered "equivalents" until applicant clarify the "means for" step with sufficient structure/material/acts for achieving the specified function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 30, 35, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doretti et al. in view of Magnotti et al. (Clinica Chimica Acta, 1988;315:315-332), and further in view of Ellman et al. (Biochemical Pharmacology 1961;7:88-95).

Doretti et al. teach what is above.

Doretti et al. do not explicitly teach use of the sensor in a handheld device with a cartridge.

Magnotti et al. teach the reagents (see pages 317-318) needed for the testing device and the advantages to develop a portable and convenient device/kit (read on as handheld) with stable, premixed reagents (read on as cartridge) to measure cholinesterases in a field assay (see abstract and also page 329, 3rd full paragraph) because field monitoring erythrocyte and plasma

cholinesterase activities is beneficial to agricultural workers and others at risk for pesticide exposure (see page 331, 2nd full paragraph).

Ellman et al. teach a new and rapid colorimetric determination of acetylcholinesterase activity which is later developed into the Test-Mate OP kit by EQM Research Inc., Cincinnati, OH, USA (as stated on page 1078, lines 11-14 of Paz-y-Mino et al. Environmental Health Perspectives 2002;110:(1077-1080)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to develop a handheld device with a biosensor (as taught by Doretti et al.) and a cartridge (whose convenience is suggested by Magnotti et al.) to monitor enzyme activity because Doretti et al. teach a biosensor to detect enzyme activity, and Magnotti et al. teach the reagents that are needed for the enzyme assay and suggest to develop a portable and convenient device to monitor cholinesterases activity in the field. One would have been motivated to make the modification because Magnotti define the optimal criteria for field measurement of cholinesterase (see page 328, 1st paragraph of Discussion) and the need for a portable/handheld device/kit with stable, premixed reagents (cartridge), and would reasonably have expected success because Doretti et al. teach how to made a biosensor for cholinesterase detection, and Magnotti et al. teach many advantages of developing a portable, convenient and stable assay system to be used in the field.

The Test-Mate OP system has all the components that are required for the detection of cholinesterase as described by Ellman et al., thus it would have been obvious to one of ordinary skill in the art to use the Test-Mate OP kit to detect, measure or monitor the activities or concentrations of cholinesterase instead of the claimed device.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 1/14/2009 have been fully considered but they are not persuasive.

Applicant argues that the device of Doretti does not teach or suggest the claimed invention because the device is not capable of measuring a protein or a plurality of proteins in a sample.

It is the examiner's position that the present invention claims a device with means for adding/measuring/determining, however the "means for" are not modified by sufficient structure, material, or acts for achieving the specified function, thus it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). Doretti's teaching of measuring reaction rates is considered "equivalents" until applicant clarify the "means for" step with sufficient structure/material/acts for achieving the specified function.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier

communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,Jon Weber can be reached at (571) 272-0925.

/Bin Shen/

Art Unit 1657

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657